

JAN 14 2000

TECH CENTER 1600/2900
ATTORNEY DOCKET NO. 16016.0005
SERIAL NO.08/813,829

NE.
In Claims 1 and 4, line 5, immediately after the word "has", delete the word "all" and immediately after the word "the", delete the word "essential".

REMARKS

Claims 1 and 4 have been amended hereinabove to clarify the invention as discussed with Examiner Clark during a December 21, 1999 telephone interview. No new matter is added by these clarifying amendments which are supported throughout the application. Applicant's attorney appreciates the time and courtesy extended by the Examiner during the interview.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1-4 stand rejected under 35 U.S.C. §112, first paragraph, allegedly because the specification does not provide reasonable enablement for mammalian non-murine embryonic stem cells. As discussed during the interview, the claims as amended are consistent with the allowed claims in the parent U.S. Patent No. 5,690,926. The enablement of the claimed invention is clear from the specification. In addition, enclosed herein as Exhibit A is WO 97/25412 by Anderson and Shim, which shows that the method described in the subject application was used successfully to isolate porcine pluripotential cells (see Page 11, lines 7-22 and Page 23, lines 23-31). The International Search Report included in WO 97/25412 cites U.S. Patent No. 5,453,357 (issued from the parent application to which the instant application claims priority) as an "X" reference against all claims, i.e. a document of particular relevance which alone appears to render the claims non-novel and non-inventive. While the Anderson and Shim

reference suggests that one of the growth factors (LIF) may not be essential, a more recent, peer-reviewed publication by Piedrahita et al. (abstract attached as Exhibit B) confirms the importance of LIF in producing pluripotential cells that can give rise to animal chimeras, which is the definitive proof of pluripotency.

Further, enclosed herein as Exhibit C is an article from *The Scientist* newspaper (issue dated September 29, 1997) wherein it is stated that the method of Applicant (i.e. Dr. Hogan), was adopted by Dr. John Gearhart of Johns Hopkins University to obtain pluripotent cells from human embryos. Thus, it is evident from these Exhibits that Applicant's method was enabled sufficiently to allow others to derive cells from diverse mammalian species.

It is Applicant's understanding from the interview and the Interview Summary that the rejection under 35 U.S.C. §112 would be withdrawn.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-4 stand rejected under 35 U.S.C .§112, second paragraph allegedly for being indefinite. Specifically, the phrase "multiple differentiated cell phenotypes" was alleged to be indefinite. As discussed in the interview, "multiple differentiated cell phenotypes" was deemed definite in U.S. Patent No. 5,453,357 as it exists in the issued claim language. For the sake of clarifying the record, "multiple differentiated cell phenotypes" means the cells can give rise to differentiated cells with multiple phenotypes. Since the meaning is the same as the language suggested by the Examiner, as discussed in the interview, no amendment of this claim language is necessary.

As to the remaining rejections under 35 U.S.C. §112, the claims have been herein amended, consistent with the discussion in the interview. In view of these amendments, the rejections under 35 U.S.C. §112, second paragraph are believed to be rendered moot.

Double Patenting Rejection

A Terminal Disclaimer over U.S. Patent No. 5,453,357 is being filed concurrently herewith. With the filing of this Disclaimer, this rejection is rendered moot.

Priority

The Office Action indicates that the subject application is not entitled to priority of U.S. Serial No. 07/958,562, since the earlier application is allegedly insufficient to comply with 35 U.S.C. §112, first paragraph. As discussed during the interview, Applicant respectfully traverses this rejection.

Firstly, applicants respectfully point out that U.S. Serial No.07/958,562 matured into U.S. Patent No. 5,453,357. Applicant notes that U.S. Patent No. 5,453, 357 was stated in the subject Office Action to render the subject claimed invention obvious. As a result, the Examiner has required a terminal disclaimer in view of U.S. Patent No. 5,453, 357, which applicants have provided herein. It is entirely inconsistent for the Examiner to claim that the same patent, while rendering the subject claimed invention obvious, does not provide enablement under 35 U.S.C. §112, first paragraph. Thus, the only issue is if there is written support in the earlier application

for the claims. Such support clearly exists, for example at Column 3, lines 44-49, Column 4, lines 9-14, and from Column 7, line 10 through Column 8, line 16.

Secondly, enclosed herein as Exhibit A and Exhibit B, are two references showing that the method described in the subject application was used successfully to isolate porcine pluripotential cells. Finally, enclosed herein as Exhibit C is an article from *The Scientist* newspaper (issue dated September 29, 1997) wherein it is stated that the method of Applicant (i.e. Dr. Brigid Hogan), was adopted by Dr. John Gearhart of Johns Hopkins University to obtain pluripotent cells from human embryos. Thus, very clearly, Applicant's method has been and can be utilized to derive cells from diverse mammalian species. Therefore, Applicant's claimed invention is enabled in U.S. Serial No. 07/958,562, and priority should be granted.

Rejection under 35 U.S.C. §102

Claims 1-3 stand rejected in view of Wheeler. In view of Applicant's priority to U.S. Serial No. 07/958,562, which was filed October 8, 1992, Wheeler, filed on May 14, 1993, is not prior art. Therefore, this rejection should be withdrawn.

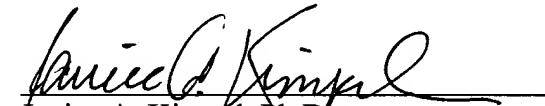
Pursuant to the above remarks, allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

ATTORNEY DOCKET NO. 16016.0005
SERIAL NO.08/813,829

A petition for a three-month extension of time and a check in the amount of \$490.00, covering the statutory fee under 37 C.F.R. §1.20(d) for a terminal disclaimer and the fee for a three-month extension of time, are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

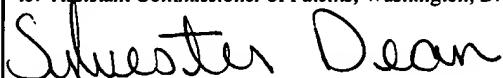
NEEDLE & ROSENBERG, P.C.


Janice A. Kimpel, Ph.D.
Registration No. 42,734

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811
Phone: (404) 688-0770

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231, on this 3rd day of January, 2000.


Sylvester Dean
Sylvester Dean

1/3/00
Date